

**Amendment and Response**

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Serial No.: 10/772,989

Confirmation No.: 5392

Filed: February 5, 2004

For: NOVEL LEAD FIXTURE MEANS

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**Remarks**

The Office Action of June 11, 2010 has been received and reviewed. In this response claim 31 has been amended, claim 37 has been added, and no claims have been cancelled. Upon entry of the new claim, claims 3-4, 7, 11-12, 18, 20-24, 26-28, 30-35, and 37 will be pending. Reconsideration and withdrawal of the rejections are respectfully requested as discussed herein.

**Lampadius (DE 2453840)**

A copy of a translation of Lampadius (DE 2453840) has been included in the Information Disclosure Statement filed herewith. Please note that this translation of Lampadius was conducted by a professional translation service -- i.e., it is not a machine translation. Further, portions of Lampadius relied upon in the remarks provided herein may not be found, or at least are not very clear within the machine translation of Lampadius, but are present in the professional translation of Lampadius included in the Information Disclosure Statement filed herewith.

**Allowed Claims**

Applicants acknowledge the notification that claims 3-4, 7, and 11-12 have been allowed.

**Claim Amendment**

Claim 31 as amended is now an independent claim that includes many of the recitations found in claim 18 (upon which claim 31 formerly depended).

Entry and consideration of amended claim 31 are respectfully requested.

**New Claim**

New claim 37 has been presented herein. Support for this new claim may be found in the application as filed at, e.g., paragraphs [0015] & [0034]-[0035].

Applicants submit that new claim 37 is patentable over Lampadius (DE 2453840) and the other various references cited in the §103 rejections in the Office Action for at least the reason

that Lampadius does not teach a glue segment comprising an unencapsulated tissue adhesive disposed at a distal end of said lead as recited in new claim 37.

Entry and allowance of new claim 37 are respectfully requested.

### **The 35 U.S.C. §103 Rejections**

#### **Claims 18, 20, 23-24, 27, 30-32, and 35**

Claims 18, 20, 23-24, 27, 30-32, and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lampadius (DE 2453840) in view of Starksen (U.S. Patent No. 5,571,161). Applicants respectfully disagree with this rejection and the assertions made in support of it.

It has been asserted in the Office Action that Lampadius teaches all the elements of independent claim 18 but "is silent as to the guard having a smaller diameter than a catheter" and that "[a]ttention is directed to the secondary reference of Starksen, which discloses a guide catheter 10 with a lumen wide enough to accommodate cardiac leads." *Office Action*, June 11, 2010, page 4. In an effort to combine the teachings of the Lampadius and Starksen, it has been further asserted in the Office Action that "it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify Lampadius to utilize a catheter as described in Starksen" and "that in order to achieve this, the guard would have to have a smaller diameter than the inner diameter of the catheter." *Office Action*, June 11, 2010, pages 4-5.

In essence, the Examiner has proposed modifying the system of Lampadius, which includes an electrode catheter and a delivery catheter, with the teachings of Starksen such that the allegedly equivalent guard of Lampadius is of a third diameter that is larger than a first diameter of the electrode catheter of Lampadius and smaller than a second diameter of the delivery catheter of Lampadius.

Figures 1 and 3 of Lampadius are reproduced below for reference in connection with the remarks presented herein.

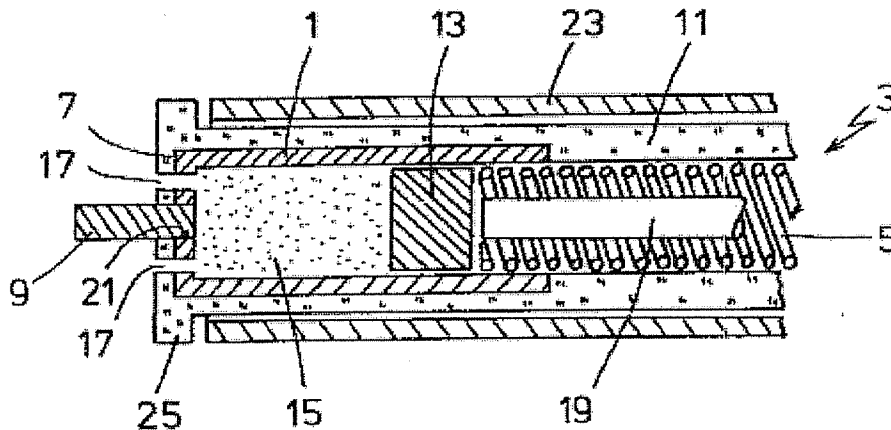


Fig. 1

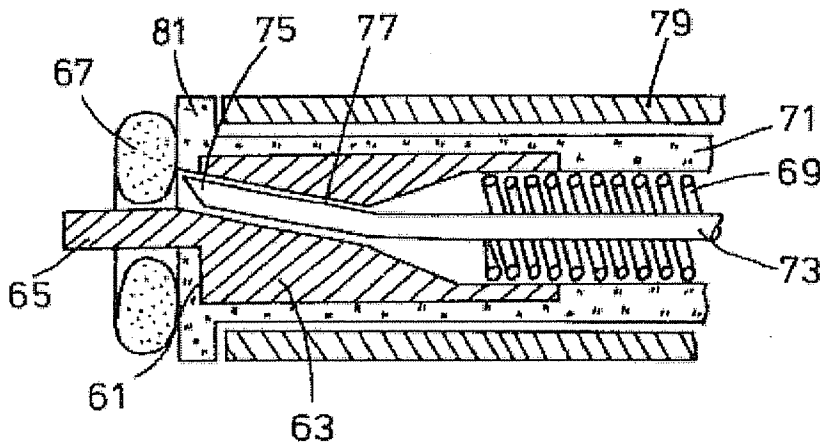


Fig. 3

In support of the obviousness rejection of claims 18, 20, 23-24, 27, 30-32, and 35, it has been proposed that either (1) the projecting edges 25, 81 of Lampadius (which have been allegedly equated to the claimed guard) would be modified to have smaller diameters than the guide catheters 23, 79 or (2) the guide catheters 23, 79 of Lampadius (which have been allegedly equated to the claimed delivery catheter) would be modified to have larger diameters than the projected edges 25, 81.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

M.P.E.P. §2143.01(V) (*citing In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984)).

Applicants respectfully submit that the proposed modification of the system of Lampadius with the teachings of Starksen would render the system of Lampadius unsatisfactory for its intended purpose, and as a result, the proposed combination of Lampadius and Starksen cannot form a *prima facie* case of obviousness with respect to claims 18, 20, 23-24, 27, 30-32, and 35.

The intended purpose of the system of Lampadius is adhesion of an electrode catheter to a tissue surface, which is accomplished through the interaction between the projecting edges 25, 81 of the electrode catheters 3 and the distal ends of the guide catheters 23, 79. More specifically, the projecting edges 25, 81 and the guide catheters 23, 79 of Lampadius work together to provide pressure to empty the adhesive containers of the electrode catheters 3 and to push the distal end of the electrode catheters 3 against a tissue surface.

For example, in the first two embodiments of Lampadius, the guide catheter 23 holds the electrode catheter 3 stationary by interfacing with the projecting edge 25 while a mandrel is advanced distally to push adhesive out of the electrode catheter 3. Further, in the third embodiment of Lampadius, the guide catheter 79 pushes against the projected edge 81 to compress the adhesive container 67 and the distal end of the electrode catheter 3 against a tissue surface to empty the adhesive container 67. As a result, the relative sizes of the diameters of the guide catheters 23, 79 and the projecting edges 25, 81 of the electrode catheters 3 as depicted in Lampadius are required to accomplish the intended purpose of the system of Lampadius.

If either of the diameters of the guide catheters 23, 79 and the projecting edges 25, 81 of the electrode catheters 3 of Lampadius were modified with the teachings of Starksen as proposed in support of this obviousness rejection, the Lampadius apparatus would be rendered unsatisfactory for its intended purpose. More specifically, the distal ends of the guide catheters 23, 79 and the projecting edges 25, 81 of the electrode catheters 3 would not work together to provide the pressure required to empty the adhesive containers of the electrode catheters or to push the distal ends of the electrode catheters 3 against a tissue surface. As such, the proposed modification of the system of Lampadius with the disclosure of Starksen to teach the recitations of independent claim 18 (from which claims 20, 23-24, 27, 30-32, and 35 depend) would render the system of Lampadius unsatisfactory for its intended purpose.

For at least these reasons, Applicants submit that the disclosures of Lampadius and Starksen fail to provide a *prima facie* case of obviousness with respect to claims 18, 20, 23-24, 27, 30-32, and 35. Reconsideration and withdrawal of the obviousness rejection of claims 18, 20, 23-24, 27, 30-32, and 35 over Lampadius in view of Starksen are, therefore respectfully requested.

#### Claim 21

Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lampadius and Starksen in view of Munch et al. (U.S. Patent No. 6,463,335). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Dependent claim 21 depends from independent claim 18. As discussed above, the combination of Lampadius and Starksen does not support a *prima facie* case of obviousness with respect to independent claim 18. No assertion has been made that Munch et al. addresses the shortcomings of the combination of Lampadius and Starksen with respect to independent claim 1 as would be need to establish a *prima facie* case of obviousness with respect to dependent claim 21.

For at least these reasons, Applicants submit that a *prima facie* case of obviousness has not been established for claim 21 over Lampadius and Starksen in view of Munch et al. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claim 28

Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lampadius and Starksen in view of Williams et al. (U.S. Patent No. 6,516,230). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Dependent claim 28 depends from independent claim 18. As discussed above, the combination of Lampadius and Starksen does not support a *prima facie* case of obviousness with respect to independent claim 18. No assertion has been made that Williams et al. addresses the shortcomings of the combination of Lampadius and Starksen with respect to independent claim 1 as would be needed to establish a *prima facie* case of obviousness with respect to dependent claim 28.

Further, claim 28 recites that the tip electrode is formed from a helix-coil. It has been asserted in the Office Action that "Lampadius is silent as to using a tip electrode shaped as a helix coil" and "it would have been obvious to one of ordinary skill in the art to substitute the helix electrode of Williams for the tip electrode of Lampadius since both are known tip electrode configurations, and the helix electrode has the benefit of providing additional anchoring at the treatment site." *Office Action*, June 11, 2010, page 6.

Contrary to the assertions in the Office Action, Lampadius is not silent as to using a tip electrode shaped as a helix. Rather, Lampadius teaches that one of the "tasks" of the invention of Lampadius is "to provide a pacemaker electrode . . . , which, in order to avoid injury, functions without the use of brushes, hooks or spirals." *Lampadius Translation*, page 5, lines 5-7 (emphasis added). Therefore, Lampadius teaches away from the use of a tip electrode that is formed from a helix-coil as recited in claim 28, and as such, one of ordinary skill in the art would not be motivated to modify the electrode catheter of Lampadius with the teachings of Williams et al. as proposed in support of the rejection of claim 28.

For at least these reasons, Applicants submit that a *prima facie* case of obviousness has not been established for claim 28 over Lampadius and Starksen in view of Williams et al. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claim 33

Claim 33 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lampadius and Starksen in view of Igo et al. (U.S. Patent No. 6,666,844). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Dependent claim 33 depends from independent claim 18. As discussed above, the combination of Lampadius and Starksen does not support a *prima facie* case of obviousness with respect to independent claim 18. No assertion has been made that Igo et al. addresses the shortcomings of the combination of Lampadius and Starksen with respect to independent claim 1 as would be needed to establish a *prima facie* case of obviousness with respect to dependent claim 33.

For at least these reasons, Applicants submit that a *prima facie* case of obviousness has not been established for claim 33 over Lampadius and Starksen in view of Igo et al. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claim 34

Claim 34 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lampadius and Starksen in view of Sigg et al. (U.S. Patent No. 6,931,286). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Dependent claim 34 depends from independent claim 18. As discussed above, the combination of Lampadius and Starksen does not support a *prima facie* case of obviousness with respect to independent claim 18. No assertion has been made that Sigg et al. addresses the shortcomings of the combination of Lampadius and Starksen with respect to independent claim 1 as would be needed to establish a *prima facie* case of obviousness with respect to dependent claim 34.

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For at least these reasons, Applicants submit that a *prima facie* case of obviousness has not been established for claim 34 over Lampadius and Starksen in view of Sigg et al. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

**Summary**

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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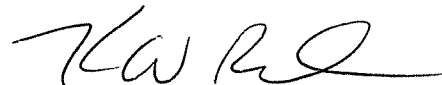
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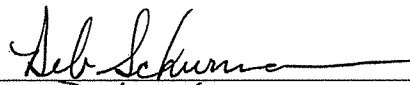
12 OCTOBER 2010  
Date

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**CERTIFICATE UNDER 37 C.F.R. §1.8:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 C.F.R. §1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12th day of October, 2010.

By:   
Name: Deb Schurmann

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